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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,602	05/08/2008	Omer Einav	414/05340	3688
67801	7590	01/11/2012	EXAMINER	
MARTIN D. MOYNIHAN d/b/a PRTSI, INC. P.O. BOX 16446 ARLINGTON, VA 22215			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	
			MAIL DATE	DELIVERY MODE
			01/11/2012	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,602	<b>Applicant(s)</b> EINAV ET AL.	
	<b>Examiner</b> FRANCES OROPEZA	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 10/17/11 (Response).
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5)  Claim(s) 1-48 is/are pending in the application.
  - 5a) Of the above claim(s) 24,26-30 and 42-46 is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 1-23,25,31-41,47 and 48 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date See Continuation Sheet.
- 4)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/27/11, 8/2/11, 8/10/11, 8/17/11, 8/30/11, 9/14/11, 9/19/11, 9/26/11, 10/11/11; 10/24/11; 10/31/11; 11/8/11; 11/29/11; 12/6/11.

**OFFICE ACTION**

***Response***

1. The Applicant arguments filed 10/17/11 have been fully considered and are discussed in greater detail below. When the initial Office action was mailed, the Examiner unfortunately failed to include an important citation, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs which makes only a minor change to the current rejection.

2. Claims 1-23, 25, 36-41, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0208246 to Kotlik et al., hereafter Kotlik in view of U.S. Patent No.6,839,594 to Cohen et al., hereafter Cohen.

As to claims 1 and 31, Kotlik discloses a method and apparatus for treating a paretic body part (paragraph 0002), the apparatus comprising: an electromyography (EMG) sensor (paragraph 0077, line 16), a neuromuscular electrical stimulation device (NMES) (0077, line 10), and a controller (paragraph 0022). The controller defines the amplitude of the stimulation pulse to the paretic voluntary muscle based in part on the electromyogram (EMG) measurement (paragraph 0014) and the neuromuscular stimulation storage (paragraphs 0014, 0073), the stimulation pulse not sufficient on its own to move the paretic body part in the desired fashion as a portion of the stimulation impulse is provided by the EMG impulses of the patient and a portion of the stimulation impulse is provided by the apparatus such that the combination of the impulses produces the motion of the paretic body part in the desired fashion.

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As to claims 2 and 37, Kotlik discloses the movement of the paretic body part reflects the movement /timing of a health body part as judged by the therapist (paragraph 0073, 0086 – line 10), hence the at least one muscle to the healthy part corresponds to the at least one muscle of the paretic part.

As to claim 3 and 38, Kotlik discloses processing the EMG signal and determining the amplitude of the NMES signal (paragraph 0014).

As to claim 4, Kotlik discloses the movement of the paretic body part reflects the movement of a health body part (paragraph 0073, 0086 – line 10).

As to claim 5, Kotlik discloses the movement of the paretic body part reflects the movement of a health body part (paragraph 0073, 0086 – line 10), hence the amplitude of the stimulation to the paretic part increases when the EMG from the healthy part increases.

As to claims 8 and 10, Kotlik discloses a plurality of EMG sensors applied to different muscles (abstract - line 6; paragraph 0011) .

As to claim 9, Kotlik discloses each EMG sensor produces a separate EMG signal (paragraph 0077 – line 15).

As to claim 11, Kotlik discloses the movement of the paretic body part reflects the movement of a health body part (paragraph 0073, 0086 – line 10) and a plurality of EMG sensors applied to different muscles (abstract - line 6; paragraph 0011).

As to claim 12, Kotlik discloses a plurality of EMG sensors applied to different muscles (abstract - line 6; paragraph 0011) and processing the EMG signals and determining the amplitude of the NMES signals (paragraph 0014).

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As to claims 13, 40 and 41, Kotlik discloses the movement of the paretic body part reflects the movement of a health body part (paragraph 0073, 0086 – line 10), a plurality of EMG sensors applied to different muscles (abstract - line 6; paragraph 0011), and processing the EMG signals and determining the amplitude of the NMES signals (paragraph 0014).

As to claim 19, Kotlik discloses the stimulation amplitude is at least partly dependent on a processed form of the ECG signal (paragraph 0078).

As to claims 20-22, Kotlik discloses system component the perform or are capable of performing signal processing to alter the timing, spreading or time delay of the EMG signal (paragraph 0078), and to produce an EMG signal that is a mirror image of the motion of the health part (paragraph 0086)

As to claim 39, Kotlik discloses the paretic body part is move in the pattern provided by the health part, while the NMES is applied to determine the parameters of treatment (paragraph 0094).

As discussed in the previous eleven paragraph of this action, Kotlik discloses the claimed invention except for:

- the healthy movement being determined from a healthy body part of the same type as the paretic type (claim1)
- the paretic body comprises an antagonistic pair of muscles (claim 6),
- the controller and NMES device to store an amplitude is high enough to cause the muscle to contract in response to nerve impulses from the brain (claim 7),

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- the paretic part is a pair, an arm, a leg, belonging to a patient , belonging to a different person (claims 14-18, 36, 47,48), and
- a first and second position sensing device (23,25).

As to claims 1, 4-18, 36, 47 and 48, Cohen discloses neural stimulation of the healthy body part which is a limb, an arm, a leg, part of a pair of arms or legs (claims 14, 15, 16, 47, 48) (patent title "Limbs"), the limb being a part of the patient (claims 1, 17, 36) or a different person (claims 18, 36) whose healthy movement pattern is learned thorough the patient and different people to providing the neural network with different stimulation protocols. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation of the limbs, arm and/ or leg, using patterns learned from the patient or different people in the Kotlik system in order to enable the stimulation pattern for the patient to be optimized based on a variety of different protocols (column 5, line 7-31; column 14, lines 30-42; column 15, lines 22-48).

As to claim 6, Cohen discloses neural stimulation of antagonistic pair of muscles for the purpose of detailed understanding of the muscle action. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used information from and antagonistic pair of muscles in the Kotlik system in order to enable the system to learn the electrical activity associated with antagonistic muscle activity so the stimulation pattern for the patient may be optimized (column 9, lines 30-36).

As to claim 7, Cohen discloses neural stimulation of muscles by the brain for the purpose of addressing this type of muscular stimulation for each individual patient. It would have been obvious to one having ordinary skill in the art at the time of the invention to have considered and

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made a protocol for stimulation of the muscles by the brain in the Kotlik system in order to enable the system to effectively respond to brain stimulation scenarios and provide appropriate stimulation customized for the individual (column 1, lines 26-28).

As to claims 23 and 25, Cohen discloses neural stimulation using sensors for the purpose determining the position of healthy body parts. It would have been obvious to one having ordinary skill in the art at the time of the invention to have sensed the healthy body part position in the Kotlik system in order to aid in the training of the neural network so optimal movement protocols and documented and implemented (column 3, lines 1-4; column 5, lines 16-32).

The arguments in the Applicant's response filed 10/17/11 have been fully considered. Contrary to the Applicant's assertion, Cohen does teach using a healthy body part of the same type as the paretic body part and shown in column 14, lines 30-42.

The Applicant asserts Kotlik teaches away from using a healthy body part to measure the motion and use this motion to model for the paretic part. The Examiner respectfully disagrees. Kotlik teaches using the same electrodes to measure and stimulate a limb, hence measuring and stimulating the paretic limb. Kotlik in no way states or implies the use of a healthy limb to measure the motion and use this motion to model for the paretic is unacceptable. Measurement and modeling from a healthy limb is simply not a means used by Kotlik to rehabilitate the limb. The teaching by Cohen of using a healthy co-lateral limb to measure and model the action for the paretic limb is an alternate protocol that could be used by Kotlik to rehabilitate a limb when, for example, the paretic limb was unable to respond at all, unable to provide a measurement and contribution to the motion, hence making the treatment by the Kotlik invention impossible.



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The Applicant asserts Kotlik teaches away from using a healthy body part to measure the motion and use this motion to model for the paretic part because in the background section of the Kotlik patent, it states rehabilitation efforts are usually focused on teaching still functioning limbs to carry out the function of the affected limbs and the devices to date that stimulate paretic parts have been unacceptable for a number of reasons including cost and functionality (column 1, lines 39-49). The Examiner finds Kotlik in no way states or implies the use of a healthy limb to measure the motion and use this motion to model for the paretic is unacceptable or inappropriate. This type of statement concerning the shortfalls in the current technology is typically found in a patent in the background section to provide an understanding of how the invention described therein is an improvement over the status quo.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES OROPEZA whose telephone number is (571) 272-4953. The examiner can normally be reached on Monday and Tuesday from 9 AM to 7 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno, can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/FRANCES OROPEZA/  
Examiner, Art Unit 3766/  
December 7, 2011

/CARL H LAYNO/

Supervisory Patent Examiner, Art Unit 3766